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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,924	06/28/2001	Avi J. Ashkenazi	P1134R2C1	1667

9157 7590 06/11/2003

GENENTECH, INC.
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SOUTH SAN FRANCISCO, CA 94080

EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/894,924	ASHKENAZI ET AL.
	Examiner	Art Unit
	Claire M. Kaufman	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 21 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14 and 67-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14 and 67-84 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 21 March 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

The amendment filed 3/21/03 has been entered.

Response to Amendment

5 The rejection of claims 14 and 67-70 under 35 USC 112, first paragraph, is withdrawn in view of the amendment to the claims.

 The rejection of claims 14 and 67-84 under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

10 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

 The formal drawings were received on 3/21/03. These drawings are acceptable for examination.

15 ***Double Patenting***
 Claims 14 and 67-83 remain provisionally rejected under the judicially created doctrine of double patenting over claims 67-84 of copending Application No. 09/896,096 for the reasons of record set forth in the previous Office action (paper #6) on page 3.

20 Claim 84 remains provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/896,096 patented for the reasons of record set forth in the previous Office action (paper #6) on page 3.

25 Applicant's intention of addressing these rejections once the claims are otherwise allowable is acknowledged.

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Priority

Applicant's arguments directed to benefit of priority of the instant application are currently moot, as the prior art applied below has a filing date earlier than Applicant's earliest priority application's filing date.

5

Claim Rejections - 35 USC § 102

Claims 14, 67-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Emery et al. (US Patent 5,885,800, cited by applicants) as evidenced by US Patent 4,946,778 for the reasons of record set forth in the previous Office action (paper #6) on pages 6-7.

10

Applicant argues that the Emery patent discloses only sequences for TR4 and speculative and prophetic uses for TR4. Neither does Emery teach one skilled in the art what ligand(s) binds to TR4 nor are DcR3 antibodies taught or suggested. The argument has been fully considered, but is not persuasive. While there are no actual examples of antibodies by Emery et al., the concept of antibodies that bind TR4 and methods of making such antibodies are taught (col. 3, lines 22-27, and col. 10, line 58 to col. 11, line 28). An actual reduction to practice is not required for this to be an anticipatory reference. While Emery et al. does not single out Fas Ligand as binding TR4, it does list it among the ligands that bind the receptors of the superfamily to which TR4 belongs. According to MPEP § 2122, utility need not be disclosed a in reference.

15 "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but no utility need be disclosed by the reference. In re Schoenwald, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)." Further, as stated in MEPE § 2121.01, the courts have found that:

20 "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention not novel' or anticipated' within section 102, the stated test is whether a reference contains an enabling disclosure'... ." In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the

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claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) In the instant case, Emery et al. provides all that is necessary for the artisan of ordinary skill at the time the invention was made to make the claimed antibodies.

5

Claim Rejections - 35 USC § 103

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Emery et al. (US Patent 5,885,800, cited by applicants) and US Patent 4,946,778 for the reasons of record set forth in the previous Office action (paper #6) on pages 7-8.

10 Applicant argues that, as argued above, Emery et al. does not meet the requirements of enablement and utility under 35 USC 101/112, first paragraph. Therefore, the second US Patent (4,946,778) is insufficient to fill in gaps left by Emery et al. related to detectable labels for antibodies. The argument has been fully considered, but is not persuasive. For the reasons discussed above for the arguments of the rejection under 35 USC 102, Emery et al. disclose all
15 that is needed to anticipate (or render obvious) the instantly claimed antibodies. Utility is not required and Emery et al. enabled in accordance with Court interpretation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of
20 time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period
25 will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or
10 informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. Please advise the examiner at the telephone number above before facsimile transmission.

15

Claire M. Kaufman, Ph.D.

Claire M. Kaufman

Patent Examiner, Art Unit 1646

June 9, 2003

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Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER